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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 136

Guidelines Establishing Test Procedures for the Analysis of Pollutants

CFR Correction

In Title 40 of the Code of Federal Regulations, parts 136 to 149, revised as of July 1, 1997, page 17, § 136.3, Table 1C, entry 53, "2,3" is corrected to read "2,4".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300700; FRL 6023-8]

RIN 2070-AB78

Triasulfuron; Pesticide Tolerance

AGENCY: Environmental Protection

Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of triasulfuron [3-(6-methoxy-4-methyl-1,3,5-triazin-2-yl)-1-(2-(2-

chloroethoxy)phenylsulfonyl)urea] in or on cattle, kidney; goat, kidney; grass, forage; grass, hay; horse, kidney; and sheep, kidney. Novartis Crop Protection, Inc., requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective August 18, 1998. Objections and requests for hearings must be received by EPA on or before October 19, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300700], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified

by the docket control number, [OPP–300700], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM#2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300700]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–5697; e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 29, 1998 (63 FR 29401), (FRL 5791–2) EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 3F4225) for tolerance by Novartis Crop Protection Inc., P.O. Box 18300, Greensboro, North Carolina 27419–8300. This notice included a summary of the petition prepared by Novartis Crop Protection Inc., the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.459 be amended by establishing a permanent tolerance for residues of the herbicide triasulfuron in or on cattle, kidney at 0.5 parts per million (ppm); goat, kidney at 0.5 ppm; grass, forage at 7.0 ppm; grass, hay at 2.0 ppm; horse, kidney at 0.5 ppm, and sheep, kidney at 0.5 ppm.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. Threshold and non-threshold effects. For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the "no-observed effect level" or "NOEL").

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a "safety factor") of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than